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OFFICE OF PETITIONS

In re Patent No. 7,372,941 : ON PETITION
Ivanisevic et al. : UNDER 37 CFR 1.183
Issue Date: May 13, 2008 : and
Application No. 10/635,113 : ON REQUEST FOR RECONSIDERATION
Filed: August 6, 2003 : OF PATENT TERM ADJUSTMENT
Attorney Docket No. 09013. :
0006-00000 :
:

This is a decision on the petition under 37 C.F.R. 1.183, requesting that the Office suspend the rules and consider on the merits a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d) filed more than two months from the date the above-referenced patent issued and on the Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d), both of which were filed on November 7, 2008.

The petition under 37 CFR 1.183 is **dismissed**.

The request for reconsideration of patent term adjustment under 37 CFR 1.705(d) is **dismissed as untimely filed**. The petition fee of \$200.00 will be charged to deposit account no. 06-0916.

Any request for reconsideration, whether directed to the decision on petition under 37 CFR 1.183 or to the decision on application for patent term adjustment under 37 CFR 1.705(d), must be filed within two months of the mailing date of this decision. Extensions of time under 37 CFR 1.136 are not permitted. See § 1.181(f).

BACKGROUND

On May 13, 2008, the above-identified application matured into U.S. Patent No. 7,372,941, with a revised patent term adjustment of 494 days. No request for reconsideration of the patent term

adjustment indicated in the patent was filed within two months of the date the patent issued. Patentees now petition under 37 C.F.R. § 1.183 to (i) suspend or waive the requirement of 37 C.F.R. § 1.705(d) that a Request for Reconsideration of Patent Term Adjustment be filed within two months of the date the patent issued; and (ii) consider the enclosed Request for Reconsideration of Patent Term Adjustment. Patentees make this request, in view of the situation presented by the recent decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008).

**ON PETITION UNDER 37 CFR 1.183
TO WAIVE THE TWO-MONTH REQUIREMENT OF 37 CFR 1.705(d)**

The above-referenced patent issued on May 13, 2008. A request for reconsideration of the patent term adjustment indicated in the patent was not filed until November 7, 2008. Petitioners request that the Office suspend the rules and consider on the merits the Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. 1.705(d) even though it was untimely filed more than two months from the date the patent issued.

The relevant regulation, 37 CFR 1.705(d), provides that:

If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, *any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b) (1) and (b) (2) of this section.* Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues. (*emphasis added*).

By the express provisions of 37 CFR 1.705(d), a request for reconsideration of patent term adjustment must be filed within two months of the date the patent issued. It is undisputed that no such request for reconsideration was filed by July 13, 2008, the date two months from the date this patent issued, May 13, 2008. Rather, on November 7, 2008, more than one month after the issuance of a decision in Wyeth v. Dudas on September 30, 2008,

petitioners filed the instant request for waiver of the two-month requirement.

37 CFR 1.183 provides that:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(f).

Preliminarily, it is recognized that the two-month requirement of 37 CFR 1.705(d) is a requirement of the regulations and not a statutory requirement. The statute, 35 U.S.C. 154, requires the Office to provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director. But, the statute allows the Director to establish the procedures for requesting such reconsideration. Those procedures¹ include pursuant to 37 CFR 1.705(d) setting a two-month period for filing a request for reconsideration of the revised patent term adjustment indicated in the patent. As such, it is within the Director's authority to waive the two-month requirement.

¹ 35 U.S.C. § 154(b)(3) provides that the USPTO shall: (1) prescribe regulations establishing procedures for the application for and determination of patent term adjustments under 35 U.S.C. § 154(b); (2) make a determination of any patent term adjustment under 35 U.S.C. § 154(b) and transmit a notice of that determination with the notice of allowance under 35 U.S.C. § 151; and (3) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination. Pursuant to the mandate and authority in 35 U.S.C. § 154(b)(3), the USPTO promulgated 37 C.F.R. § 1.705, which provides that: (1) the notice of allowance will include notification of any patent term adjustment under 35 U.S.C. § 154(b) (37 C.F.R. § 1.705(a)); (2) any request for reconsideration of the patent term adjustment indicated in the notice of allowance (except as provided in 37 C.F.R. § 1.705(d)) must be by way of an application for patent term adjustment filed no later than the payment of the issue fee and accompanied by (*inter alia*) the fee set forth in 37 C.F.R. § 1.18(e) (37 C.F.R. § 1.705(b)); and (3) if the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued.

Having considered petitioners' arguments, it is concluded that waiver of the two-month requirement is not warranted. The primary basis for requesting waiver set forth by petitioners is the situation presented by the recent decision in Wyeth v. Dudas, No. 07-1492 (D.D.C. Sept. 30, 2008). Specifically, petitioners state that in Wyeth, the U.S. District Court for the District of Columbia held that contrary to USPTO practice, a patentee is entitled to Patent Term Adjustment credit for examination delay under 37 CFR 1.702(b) in addition to any examination delay under 37 CFR 1.702(a), to the extent that the two periods of delay "do not occur on the same calendar day or days." Petitioners implicitly argue that they could not have filed a Request for Reconsideration of Patent Term Adjustment within two months of the date the above-referenced patent issued because the basis for the Request for Reconsideration of Patent Term Adjustment is the Wyeth decision, which was entered more than one month after the issuance of their patent.

First, of all, the issuance of the Wyeth Opinion is not an extraordinary situation. Wyeth followed the procedure set forth in 37 CFR 1.705 for requesting reconsideration of the patent term adjustment determination. Then, pursuant to 35 U.S.C. 154(b)(4)(A)², Wyeth timely filed a complaint in District Court seeking judicial review of the Office's decision. A Memorandum Opinion and Order, the Wyeth decision of September 30, 2008, directed to the parties involved was issued.

The fact that any relief ultimately granted in Wyeth would benefit patentees had they timely filed a request for reconsideration does not make the situation extraordinary. Petitioners chose not to challenge their revised patent term adjustment within the two-month period. The argument that patentees could not have filed a Request for Reconsideration of Patent Term Adjustment within two months of the date the above-referenced patent issued because the basis for the Request for Reconsideration of Patent Term Adjustment is the Wyeth decision,

² 35 U.S.C. 154(b)(4)(A) APPEAL OF PATENT TERM ADJUSTMENT DETERMINATION. – (A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

which was entered more than one months after the issuance of their patent, is not compelling. Petitioners could have filed a Request for Reconsideration of Patent Term Adjustment as Wyeth did. It is acknowledged that petitioners may have chosen not to file a request for reconsideration based on a conclusion that the Office's interpretation of 35 U.S.C. § 154(b)(2)(A) was correct. Nonetheless, the fact that the District Court has now issued an Opinion contrary to the Office's interpretation does not make the situation extraordinary. This is not unlike any other situation where a patentee (or applicant) challenges a final agency decision and the decision upon judicial review could have had applicability to another patentee (or applicant) had they taken such action. In fact, many patentees may be in the same situation as petitioners with respect to the Wyeth decision.

Petitioners simply fail to articulate how their failure to file a request for reconsideration of patent term adjustment within two months of the issue date of the patent was due to an extraordinary situation. Petitioners cannot rely on Wyeth's actions or the Wyeth decision to establish that their situation was extraordinary.

Moreover, justice does not require waiver of the two-month requirement. Justice requires that the Office continue to devote its resources to the adjudication of timely filed requests for reconsideration under 37 CFR 1.705(b) and (d). Further, upon ultimate resolution of the interpretation of 37 CFR 1.702, justice requires that the Office determine consistent with relevant law and practice, and appropriate Court or legislative guidance, the applicability of any changes as to all affected patentees who failed to timely seek administrative remedy, and thus, could not seek judicial review.

In addition, given that the law only allows 180-days for both the filing of a petition and for the Office's consideration of that petition petitioner's unexplained nearly two-month delay in filing the petition weighs against them. The remaining period to file a civil action does not so distinguish petitioner's situation from any other patentee who failed to meet the two-month deadline for filing a request for reconsideration of patent term adjustment determination such that justice requires waiver.

In view thereof, the petition under 37 CFR 1.183 for waiver of the two-month requirement of 37 CFR 1.705(d) is dismissed.

Accordingly, consideration now turns to the Request for Reconsideration of Patent Term Adjustment under 37 CFR 1.705(d).

**ON REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)**

This is a decision on the "DETERMINATION OF PATENT TERM ADJUSTMENT - POST GRANT," filed November 7, 2008. Therein, patentees request correction of the patent term adjustment (PTA) indicated in the patent to one thousand and five (1005) days.

On May 13, 2008, the above-identified application matured into U.S. Patent No. 7,372,941 with a revised patent term adjustment of 494 days. The instant request for reconsideration was filed more than five months after the issuance of the patent, on November 7, 2008.

No error in the printing of the patent has been shown. The patent term adjustment indicated on the patent reflects the Office's determination of patent term adjustment shown in the PAIR system for this application. 37 CFR 1.705(d) provides the sole avenue before the Office for requesting reconsideration of the Office's determination of patent term adjustment indicated in the patent. Moreover, § 1.705(d) states that "any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section." Since the request was not filed within two months of the issue date of the patent, the request is properly dismissed as untimely filed.

CONCLUSION

The request for waiver of 37 CFR 1.705(d) pursuant to 37 CFR 1.183 is not warranted. Accordingly, the request for reconsideration of the patent term adjustment under 37 CFR 1.705(d) filed more than two months after the issue date of the patent is dismissed as untimely filed.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

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